

SUPPORT FOR THE AMENDMENTS

Claim 1 is canceled. The subject matter of Claim 1 is rewritten using wording and structure consistent with U.S. patent law practice in new Claim 16.

Claims 2-8, 10 and 14 are amended to depend from Claim 16.

Claim 11 is amended to use wording and structure consistent with U.S. patent law practice.

Claim 12 is amended to depend from Claim 17.

Support for Claim 16 is found in original Claim 1 and on page 2, lines 31-34, and page 15, lines 17-19, in the specification.

Support for Claim 17 is found in original Claim 12.

No new matter will be added to this application by entry of this amendment.

Upon entry of this amendment, Claims 2-14 and 16-17 are active.

REQUEST FOR RECONSIDERATION

The claimed invention is directed to the production of pharmaceuticals or parts of pharmaceuticals or food supplements which are spray coated with a coating agent in which pigments are incorporated. In actual practice simultaneous spray application of a coating agent and pigments is difficult if the coating agent and pigment are incompatible in the mixture to be spray applied. In such cases, shortly after addition of the pigment to the coating agent dispersion, coagulation of the dispersion takes place and as a consequence, the production process is interrupted due to blockage of the spray nozzles.

The claimed invention addresses this problem by providing a method for producing pharmaceuticals or parts of pharmaceuticals or food supplements or parts thereof, comprising: preparing a sprayable solution, suspension or dispersion of a film-forming

coating agent in a liquid; preparing a separate sprayable solution, suspension or dispersion of a pigment in a liquid; simultaneously spraying by spray application onto a substrate of the pharmaceuticals or parts of pharmaceuticals or food supplements or parts thereof with the solution, suspension or dispersion of a film-forming coating agent and the solution, suspension or dispersion of a pigment; thereby coating the substrate with the film-forming coating agent comprising the pigment; evaporating the liquid of each solution, suspension or dispersion; forming a uniformly pigmented film coating on the pharmaceuticals or parts of pharmaceuticals or food supplements or parts thereof; wherein the film-forming coating agent is a (meth)acrylate copolymer having cationic or anionic groups, the sprayable solution, suspension or dispersion of a film-forming coating agent and the sprayable solution, suspension or dispersion of a pigment are incompatible with respect to destabilization of the dispersion, coagulation, signs of inhomogeneity or similarly unwanted effects if combined before spraying, and the simultaneously spraying by spray application comprises one or more spray devices which separately spray liquids, singly or together, and separate spray beams of the one or more spray devices overlap. No such process is disclosed or suggested in the cited references.

Applicants wish to thank Examiner Le for the courteous and helpful discussion held with Applicants' U.S. representative on October 29, 2007. At that time Applicants' U.S. representative presented discussion relative to possible claim amendments and argued that the cited combination of Aletshauser and WO 00/05307 is improper and therefore cannot support a finding that the combined references render the present invention obvious. The following is intended to reiterate and expand upon that discussion.

The rejection of Claims 1-13 under 35 U.S.C. 103(a) over WO 00/05307 in view of Aletshauser et al. (Journal of Controlled Release, 27 (1993) 149-156) is respectfully traversed.

The cited references cannot be combined to support a conclusion of obviousness.

WO 00/05307 is directed to a method for producing a coating and excipient agent for oral and dermal dosage forms, wherein constituents are mixed with or without water and the agent is produced by melting, casting, spreading or spraying. Applicants respectfully note that the inventive entity of WO 00/05307 and the present application are the same. Applicants have discussed in the specification on page 2, lines 31-38, the problems encountered in practice when the method of WO 00/05307 is applied to spray application of incompatible mixtures of coating agents and pigments.

The Office has cited Abletshauser to show a simultaneous spraying of incompatible film components. The components described are film forming and cross-linking materials. Nowhere does Abletshauser disclose or suggest an incompatible combination of components comprising a film-forming coating agent and a pigment. Moreover, Abletshauser clearly describes:

“In situ formation of insoluble films by fluidized bed spraying of aqueous solutions of the film components **without any ingredients** shows promising features for further improvement of the method and can be extended to a variety of film-forming substances such as ionic and nonionic polysaccharides, proteins etc.; each combined with a specific crosslinking agent.”(page 155, last paragraph before Acknowledgement)(Bold added)

Applicants respectfully submit that Abletshauser actually **teaches away from** the spraying of a film component with ingredients such as pigments onto a substrate.

In view of the above, Applicants respectfully submit that the cited references should not be combined and therefore cannot support a conclusion of obviousness. Withdrawal of the rejection of Claims 1-13 under 35 U.S.C. 103(a) over WO 00/05307 in view of Abletshauser et al. is respectfully requested.

The rejection of Claim 14 under 35 U.S.C. 102(b) over Applicant's own admission or by Seaman et al. (U.S. 6,378,789) is respectfully traversed.

Neither reference discloses or suggests an apparatus suitable for carrying out the method of Claim 16, wherein **the separate spray beams of one or more spray devices overlap**.

The Office cites Applicants discussion on page 1, lines 10-21. This discussion states:

“are sprayed simultaneously from two separate spray nozzles onto active ingredient-containing pellets. The film application can take place for example in a fluidized bed apparatus with two spray nozzles installed therein. The method has an approximately equivalent result to sequential application of the two components, but has the advantage of saving time.”

This discussion of prior art clearly does not describe equipment wherein **the separate spray beams of one or more spray devices overlap**.

Likewise, Seaman describes a combination spray apparatus which allows for the selection of several different flowable materials to be sprayed from a single unit. The main fluid sprayed is water and the several different flowable materials are siphoned by the water flow into the nozzle where it is mixed with the water and sprayed through the nozzle. (Col. 3, lines 40, through Col. 4, line 3) Seaman does not disclose or suggest a nozzle arrangement wherein **the separate spray beams of one or more spray devices overlap**.

Applicants respectfully note that in order to support a finding of anticipation, “[e]very element of the claimed invention . . . be literally present, arranged as in the claim.” *Perkin-Elmer Corp.*, 732 F.2d at 894, 221 USPQ. Therefore the identical invention must be shown in as complete detail in the reference as is contained in the claim under examination.

As neither reference discloses or suggests an apparatus wherein **the separate spray beams of one or more spray devices overlap**, neither can anticipate or render obvious the invention according to Claim 14. Withdrawal of the rejection of Claim 14 under 35 U.S.C.

102(b) over Applicant's own admission or by Seaman et al. (U.S. 6,378,789) is respectfully requested.

The rejection of Claims 1-14 under 35 U.S.C. 112, second paragraph is obviated by appropriate amendment. Claim 1 is canceled. Claim 16 has been written to describe the invention including the description, "the sprayable solution, suspension or dispersion of a film-forming coating agent and the sprayable solution, suspension or dispersion of a pigment are incompatible with respect to destabilization of the dispersion, coagulation, signs of inhomogeneity or similarly unwanted effects if combined before spraying," as suggested by the Examiner. Claim 11 is amended to properly depend from Claim 10. Claims 12 and 13 are amended to depend from Claim 17 which describes applying a sealing layer to the substrate. Withdrawal of the rejection of Claims 1-14 under 35 U.S.C. 112, second paragraph is respectfully requested.

The rejection of Claim 14 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is respectfully traversed. Applicants respectfully submit that Claim 14 is enabled by the description in the specification beginning on page 16, line 21, and continuing to page 19, line 20. The spray device is described beginning on page 16 and bridging to page 17. Application requirements are outlined beginning on page 17 and continuing to page 18 and references describing methods and equipment which can be modified according to the invention are listed on page 18. Moreover, Examples 2 and 4 describe equipment and use of that equipment according to the claimed invention.

MPEP § 2164.04 states:

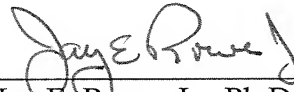
"In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention . . . A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is reason to doubt the objective truth of the statements contained therein . . ."

Applicants respectfully submit that based on the description in the specification, including the Examples, one of ordinary skill in the art can practice the invention of Claim 14, without undue experimentation and therefore withdrawal of the rejection of Claim 14 under 35 U.S.C. 112, first paragraph, is respectfully requested.

Applicants respectfully submit that the above-identified application is now in condition for allowance and early notice of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Jay E. Rowe, Jr., Ph.D.
Registration No. 58,948

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)